

510(k) Summary

OCT 04 2013

1. Date Prepared [21 CFR807.92 (a) (1)]

August 30, 2013

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor: SonoScape Company Limited
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518051, P.R.China
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3. Trade Name, Common Name, Classification [21 CFR807.92(a)(2)]

Trade Name: S8 Exp Portable Digital Color Doppler Ultrasound System
Common Name: Diagnostic Ultrasound System and Transducers
Classification:
21 CFR892.1550 Ultrasonic Pulsed Doppler Imaging System Product code: IYN
21 CFR892.1560 Ultrasonic Pulsed Echo Imaging System Product code: IYO
21 CFR892.1570 Diagnostic Ultrasonic Transducer Product code: ITX
Classification Panel: Radiology
Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicates within this submission are as follows:

SonoScape Company Limited, Portable Digital Color Doppler Ultrasound System, Model S9 has been cleared by FDA through 510(k) No.K131088 (May 24, 2013).

5. Description of the Device [21 CFR 807.92(a)(4)]

The SonoScape S8 Exp Portable Digital Color Doppler Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and

confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 3D/4D.

6. Intended Use [21 CFR 807.92(a)(5)]

The SonoScape S8 Exp device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

7. Testing

Laboratory testing was conducted to verify that the S8 Exp system with added transducer met all design specification and was substantially equivalent to the Predicate Device. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. The acoustic output is measured and calculated per "NEMA UID 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" and "NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment".

IEC 60601-1: 2005 Medical Electrical Equipment - Part 1: General Requirements for Safety

IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

IEC 60601-2-37: 2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.

NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

8. Clinical Test:

No clinical testing was required.

9. Comparison Table

The differences between the S8 Exp and the predicate device S9 in almost every part are listed in the tables below.

Table 1 Intended Use Comparison

ID	Items	Proposed Device SonoScape S8 Exp	Predicate Device SonoScape S9	Remark
1	Intended Use	The SonoScape S8 Exp device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.	The SonoScape S9 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.	Same

Table 2 General Comparison

ID	Comparison Items	Proposed Device SonoScape S8 Exp	Predicate Device SonoScape S9	Remark
2	Classification Name	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Same
3	Product Code	90-IYN/90-IYO/90-ITX	90-IYN/90-IYO/90-ITX	Same
4	Regulation Number	892.1550/892.1560/892.1570	892.1550/892.1560/892.1570	Same

ID	Comparison Items	Proposed Device SonoScape S8 Exp	Predicate Device SonoScape S9	Remark
5	Panel	Radiology	Radiology	Same
6	Class	II	II	Same
7	Probe Type & Connectors	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L752 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz 10L1 Linear Array, 6.0-12.0 MHz C611 Micro-curved Array, 4.0-8.0 MHz C311 Micro-curved Array, 2.0-4.0 MHz C344 Curved Array, 2.0-5.0 MHz C322 Curved Array, 2.0-6.0 MHz C353 Curved Array, 2.0-6.0 MHz C362 Curved Array, 2.0-6.0 MHz C354 Curved Array, 2.0-6.0 MHz C542 Curved Array, 4.0-7.0 MHz VC6-2 Curved Array, 2.0-6.0 MHz 6V1 Micro-curved Array, 4.0-8.0 MHz 6V3 Micro-curved Array, 5.0-9.0 MHz EC9-5 Micro-curved Array, 5.0-9.0 MHz BCC9-5 Micro-convex Array, 5.0-9.0MHz BCL10-5 Micro-convex Array, 5.0-10.0MHz 2P2 Phased Array, 1.0-5.0 MHz 3P1 Phased Array, 1.0-5.0 MHz 5P2 Phased Array, 3.0-8.0 MHz 8P1 Phased Array, 4.0-12.0 MHz 2P1 Phased Array, 2.0-4.0 MHz 5P1 Phased Array, 4.0-7.0 MHz Multi-port connector connects 2 transducers	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L752 Linear Array, 5.0-12.0 MHz / C344 Curved Array, 2.0-5.0 MHz C322 Curved Array, 2.0-6.0 MHz C353 Curved Array, 2.0-6.0 MHz VC6-2 Curved Array, 2.0-6.0 MHz 6V1 Micro-curved Array, 4.0-8.0 MHz 6V3 Micro-curved Array, 5.0-9.0 MHz 2P2 Phased Array, 1.0-5.0 MHz 3P1 Phased Array, 1.0-5.0 MHz 5P2 Phased Array, 3.0-8.0 MHz 8P1 Phased Array, 4.0-12.0 MHz Multi-port connector connects 2 transducers	SE Analysis 1
8	Acoustic Track	TRACK 3	TRACK 3	Same

Table 3 Functions Comparison

ID	Comparison Items	Proposed Device SonoScape S8 Exp	Predicate Device SonoScape S9	Remark
9	Design	Based on an embedded Linux operating system.	Based on an embedded Linux operating system.	Same
		Based on a 128 channel full digital beam former.	Based on a 128 channel full digital beam former.	Same
		Autocorrelation for color processing and FFT for pulse and CW Doppler processing.	Autocorrelation for color processing and FFT for pulse and CW Doppler processing.	Same
		Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz.	Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz.	Same
		Cine play back capability	Cine play back capability	Same
		Image file archive	Image file archive	Same
		Software upgrade with USB flash drive.	Software upgrade with USB flash drive.	Same
		Digital Scan Converter 800×600	Digital Scan Converter 800×600	Same
		With full keyboard panel	With touch-screen panel	SE Analysis 2
10	Operation Controls	TGC 8 slider	TGC 8 slider	Same
		Depth Range: 3 to 32 cm	Depth Range: 3 to 32 cm	Same
		Image sector size: 32 lines to full B (256 lines)	Image sector size: 32 lines to full B (256 lines)	Same
		Image Sector position: Steering within full maximum	Image Sector position: Steering within full maximum	Same
		B orientation flip :L/R key with marking on the screen	B orientation flip :L/R key with marking on the screen	Same
		B Dynamic range control: preset 14 curves over 140 dB	B Dynamic range control: preset 14 curves over 140 dB	Same
		Gray Scale Control: 7 Settings	Gray Scale Control: 7 Settings	Same
		Focal Number: 12 focal zone setting	Focal Number: 12 focal zone setting	Same
		B persistence: 0-95%	B persistence: 0-95%	Same
		Image Processing: Smoothing, edge enhancement	Image Processing: Smoothing, edge enhancement	Same
		PW sweeping speed 2,4,6,8	PW sweeping speed 2,4,6,8	Same

ID	Comparison Items	Proposed Device SonoScape S8 Exp	Predicate Device SonoScape S9	Remark
		sec over display	sec over display	
		PW Wall filter setting:16 settings,25 to 750 HZ	PW Wall filter setting:16 settings,25 to 750 HZ	Same
		PW sample volume:0.5 to 20mm	PW sample volume:0.5 to 20mm	Same
		PW/B update: with UPDATE key	PW/B update: with UPDATE key	Same
		PW cursor steering: Steer soft key	PW cursor steering: Steer soft key	Same
		PW angle correction:0 to 80 degree user control	PW angle correction:0 to 80 degree user control	Same
		PW spectrum dynamic range:10 preset curve over 15-48 dB	PW spectrum dynamic range:10 preset curve over 15-48 dB	Same
		Spectrum baseline shift and invert	Spectrum baseline shift and invert	Same
		Color ROI setting: trackball and set key to control size and position	Color ROI setting: trackball and set key to control size and position	Same
		Color steering on flat probe:±20 ±160	Color steering on flat probe:±20 ±160	Same
		Color Wall Filter: Color wall filter with 16 selection, 25-750 of PRF	Color Wall Filter: Color wall filter with 16 selection, 25-750 of PRF	Same
		Color priority-B priority soft menu	Color priority-B priority soft menu	Same
		Color Packet size: preset per Exam, horizontal, vertical, off	Color Packet size: preset per Exam, horizontal, vertical, off	Same
		Zoom adjustable	Zoom adjustable	Same
		Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Same
		Cine control: step, play backward, play continuously	Cine control: step, play backward, play continuously	Same
11	Operation Mode	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image 3D/4D Mode Color M Mode	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image 3D/4D Mode Color M Mode	Same
12	Display Modes	Dual B, Quad Display, B and M, B and Doppler	Dual B, Quad Display, B and M, B and Doppler	Same

ID	Comparison Items	Proposed Device SonoScape S8 Exp	Predicate Device SonoScape S9	Remark
		B + Color, Dual B(Flow) Triplex mode: B,CFM, and PW/CW ; B,DPI, and PW/CW;B,THI and Color M, steer M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging.	B + Color, Dual B(Flow) Triplex mode: B,CFM, and PW/CW ; B,DPI, and PW/CW;B,THI and Color M, steer M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging.	
13	Measureme nt Items	Distance; area; circumference; calipers; volume, velocity, HR, PI, RI. Cardiac. OB/GYN, Urology, Vascular and small part package	Distance; area; circumference; calipers; volume, velocity, HR, PI, RI. Cardiac. OB/GYN, Urology, Vascular and small part package	Same
14	Cine Loop	Automatic review/ manual review	Automatic review/ manual review	Same
		Review speed can be adjusted	Review speed can be adjusted	Same

Table 4 Specifications Comparison

ID	Comparison Items	Proposed Device SonoScape S8 Exp			Predicate Device SonoScape S9			Remark
15	Power Supply	Voltage: 110-240 VAC			Voltage: 110-240 VAC			Same
		Frequency: 50/60 Hz			Frequency: 50/60 Hz			Same
		Power Consumption: 110-240V AC, 2.7-1.2A			Power Consumption: 110-240V AC, 2.7-1.2A			Same
16	Operating Condition	Temperature: 10~40°C			Temperature: 10~40°C			Same
		Relative humidity: 30~75%			Relative humidity: 30~75%			Same
		Air pressure: 700hPa ~1060hPa			Air pressure: 700hPa ~1060hPa			Same
17	Storage Condition	Temperature: -20~55°C			Temperature: -20~55°C			Same
		Relative humidity: 20~90%			Relative humidity: 20~90%			Same
		Air pressure: 700hPa ~1060hPa			Air pressure: 700hPa ~1060hPa			Same
18	Screen Size	15 inch Widescreen LCD monitor			15 inch Widescreen LCD monitor			Same
19	Measurement Accuracy	Parameter	Value range	Error range	Parameter	Value range	Error range	
		Display depth	Max 32.9 cm; (Probe depend)	±3%	Display depth	Max 32.9 cm; (Probe depend)	±3%	Same

ID	Comparison Items	Proposed Device SonoScape S8 Exp			Predicate Device SonoScape S9			Remark
		Distance	0~31.0 cm	±3%	Distance	0~31.0 cm	±3%	Same
		Area	Max. ≥855 cm ²	±7%	Area	Max. ≥855 cm ²	±7%	Same
		Angle	10~193°	±3%	Angle	10~193°	±3%	Same
		Circumference	200 cm	±3%	Circumference	200 cm	±3%	Same
		Volume	Max. 25000 cm ³	±10%	Volume	Max. 25000 cm ³	±10%	Same
		M-Mode time	2,4,6,8 S	±1%	M-Mode time	2,4,6,8 S	±1%	Same
		Heart Rate	8 ~ 1000 beats/sec	±3%	Heart Rate	8 ~ 1000 beats/sec	±3%	Same
		Slope	1300 cm/s	±3%	Slope	1300 cm/s	±3%	Same
		Velocity (PW)	0.04-2940 cm/s	Angle ≤60°, ≤5%	Velocity (PW)	0.04-2940 cm/s	Angle ≤60°, ≤5%	Same
		Velocity (CW)	0.12-3795 cm/s	Angle ≤60°, ≤5%	Velocity (CW)	0.12-3795 cm/s	Angle ≤60°, ≤5%	Same
		Velocity (Color)	1-298 cm/s	Angle ≤60°, ≤5%	Velocity (Color)	1-298 cm/s	Angle ≤60°, ≤5%	Same
20	Acoustic Output	Track 3: MI, TIS, TIC, TIB Derated ispta: 720Mw/cm ² maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm ² max			Track 3: MI, TIS, TIC, TIB Derated ispta: 720Mw/cm ² maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm ² max			Same

Table 5 Safety Comparison

ID	Comparison Items	Proposed Device SonoScape S8 Exp	Predicate Device SonoScape S9	Remark
21	Electrical Safety	-IEC 60601-1	-IEC 60601-1	Same
22	EMC	-IEC 60601-1-2	-IEC 60601-1-2	Same
23	Performance	-IEC 60601-2-37	-IEC 60601-2-37	Same
24	Biocompatibility	-ISO 10993-5, -ISO 10993-10	-ISO 10993-5, -ISO 10993-10	Same
25	Level of Concern Of Software	Moderate level of concern system	Moderate level of concern system	Same

SE Analysis 1:

Probe Type, Compare to the predicate device, the proposed device is with different probe type or frequency, such as L743, 10L1, C611, C311 etc. But no new intended use is added and all of them comply with IEC 60601-2-37, NEMA UD 2-2004 and NEMA UD3: 2004, therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

SE Analysis 2:

The proposed device is with full keyboard panel and the predicate device is not, but both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Discussion of Substantially Equivalent

It is reasonable that there are some differences between our new system and its predicate. All of parameters comply with 21CFR1020.33 and related IEC standards. We did not use any new technology in this system, so those differences between our new system and its predicate do not affect the safety and effectiveness (SE).

The proposed device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device. The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

10 Substantially Equivalent Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S8 Exp Portable Digital Color Doppler Ultrasound System is substantially equivalent to predicate devices with regard to safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 4, 2013

SonoScape Company Limited
% Ms. Toki Wu
Regulatory Affairs Manager
Yizhe Building, Yuquan Road
Shenzhen, Guangdong 518051
P.R. CHINA

Re: K132768

Trade/Device Name: S8 Exp Portable Digital Color Doppler Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: August 30, 2013

Received: September 4, 2013

Dear Ms. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the "S8 Exp Portable Digital Color Doppler Ultrasound System," as described in your premarket notification:

Transducer Model Number

2P1 Phase Array	2P2 Phase Array	3P1 Phase Array
5P1 Phase Array	5P2 Phase Array	8P1 Phase Array
C611 Micro-curved Array	C311 Micro-curved Array	6V1 Micro-curved Array
6V3 Micro-curved Array	EC9-5 Micro-curved Array	BCC9-5 Micro-curved Array
BCL10-5 Biplane Array	C344 Curved Array	C353 Curved Array
C354 Curved Array	C542 Curved Array	C362 Curved Array
C322 Curved Array	VC6-2 Curved Array	L741 Linear Array
L742 Linear Array	L743 Linear Array	L752 Linear Array
	10L1 Linear Array	

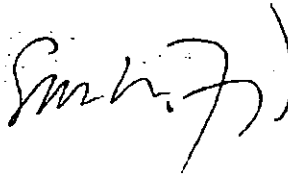
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132768

Device Name: S8 Exp Portable Digital Color Doppler Ultrasound System

Indications for Use: The SonoScape S8 Exp device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

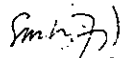
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K132768

Diagnostic Ultrasound Indications for Use Form

System: SonoScape S8 Exp
 Diagnostic Ultrasound Pulsed Echo System
 Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	N	N	N		N	N	Note 1	Notes 2,4,5
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4,5
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

 (Division Sign Off)
 Division of Radiological Health
 Office of *In Vitro* Diagnostic and Radiological Health

510(k) _____

Indications for Use

7-2

Diagnostic Ultrasound Indications for Use Form

Transducer: 2P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CW D	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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 Division of Radiological Health
 Office of *In Vitro* Diagnostic and Radiological Health

510(k) _____

Indications for Use

7-3

Diagnostic Ultrasound Indications for Use Form

Transducer: 2P2 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CW D	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2,3,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-4

Diagnostic Ultrasound Indications for Use Form

Transducer: 3P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-5

Diagnostic Ultrasound Indications for Use Form

Transducer: 5P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-6

Diagnostic Ultrasound Indications for Use Form

Transducer: 5P2 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-7

Diagnostic Ultrasound Indications for Use Form

Transducer: 8P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-8

Diagnostic Ultrasound Indications for Use Form

Transducer: C611 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-9

Diagnostic Ultrasound Indications for Use Form

Transducer: C311 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-10

Diagnostic Ultrasound Indications for Use Form

Transducer: 6V1 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

Transducer: 6V3 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-12

Diagnostic Ultrasound Indications for Use Form

Transducer: EC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: BCC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-14

Diagnostic Ultrasound Indications for Use Form

Transducer: BCL10-5 Biplane Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-15

Diagnostic Ultrasound Indications for Use Form

Transducer: C344 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-16

Diagnostic Ultrasound Indications for Use Form

Transducer: C353 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-17

Diagnostic Ultrasound Indications for Use Form

Transducer: C354 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other ^a Combined	Other ^a Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	N	N	N		N	N	Note 1	Notes 2,4
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: C542 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other ^a Combined	Other ^a Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Division of Radiological Health
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510(k) _____

Diagnostic Ultrasound Indications for Use Form

Transducer: C362 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	N	N	N		N	N	Note 1	Notes 2,4
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

Transducer: C322 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4,5
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

Transducer: L741 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P	P	P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-23

Diagnostic Ultrasound Indications for Use Form

Transducer: L742 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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510(k) _____

Indications for Use

7-24

Diagnostic Ultrasound Indications for Use Form

Transducer: L743 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: L752 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Intravascular								
	Other (Ob/GYN)								
	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
Peripheral Vessel	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-26

Diagnostic Ultrasound Indications for Use Form

Transducer: 10L1 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-27